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NATIONAL AQUACULTURE ASSOCIATION
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April 13, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Re: **Docket No. 99N-0386**

Dear Food and Drug Administration:

The National Aquaculture Association, representing a diversity of finfish and shellfish species groups, appreciates the opportunity to comment on the Food and Drug Administration's (FDA) Modernization Act targets. We respectfully submit answers to your specific questions as outlined in the Federal Register notice of March 22, 1999.

1. **What actions do you propose the agency take to expand FDA's capability to incorporate state-of-the-art science into its risk-based decision making?**

Answer: In order to expand FDA's capability to incorporate state-of-the-art science into decision making, FDA must expand its use of expert panels. These panels should include appropriate industry representatives. The panels' findings should be subject to public comment. While use of state-of-the-art science can be valuable, it must be tempered with careful analysis of its practical implications and appropriate historical perspectives. Industry representatives can frequently provide historical perspective. State-of-the-art science must be carefully evaluated along with other science subjected to repeated testing by other scientists and hence perhaps more reliable. State of the art science does not necessarily imply better science or science that can substantively assist FDA in its risk-based decision making.

2. **What actions do you propose to facilitate the exchange and integration of scientific information to better enable FDA to meet its public health responsibilities throughout a product's lifecycle?**

Answer: FDA can better meet its public health responsibilities by developing an information/technology transfer mechanism between appropriate government, academic scientists and industry. These stakeholders would be product specific. We suggest periodic product or product class reviews.

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3. **What actions do you propose for educating the public about the concept of balancing risks against benefits in public health decision making?**

Answer: Because of public trust, FDA carries a significant impact on public perceptions and understanding. Balancing FDA's public presentations regarding risk and benefit becomes a significant agency responsibility. We suggest public health decisions regarding products be thoroughly explained in the Federal Register and in press conferences. Additionally, the FDA should spend some resources directed at educating the public as to what the agency does and how it reaches its decisions.

4. **Because the agency must allocate its limited resources to achieve the greatest impact, what actions do you propose to enable FDA and its product centers to focus resources on areas of greatest risk to the public health?**

Answer: FDA must clearly define risk and explain how risk analysis is made. This may require the FDA to establish rules of risk analysis. These rules would be subject to public comment. Since risk is not the only component of FDA responsibility, the agency must not devote their entire resources in this area. Minor animal species such as fish are not an area of significant public health risk. A strict FDA focus on greatest risk would be counterproductive to assisting the industry obtain additional therapeutic agents. How to balance the needs of the general public with the needs of minor animal species groups with limited resources is problematic and should be subject to agency consideration.

5. **Because the agency wants to assure that its stakeholders are aware of and participate in its modernization activities, what additional actions do you propose for enhancing communication processes that allow for ongoing feedback and/or evaluation of our modernization efforts?**

Answer: The current Federal Register system of notification is an exceptional mode of information transfer regarding FDA activities and efforts. The ability to provide written comment and participate in modernization activities on specific issues is of utmost importance to stakeholders.

Within the context of FDA Modernization, the NAA recommends agency attention to proposals described in the FDA document "Proposals to increase the legal availability of animal drugs for minor species and minor uses." This proposal was developed by the ADAA Minor Use/Minor Species Working Group and contains proposals that could improve FDA science pertaining to minor animal species, could improve risk analysis and otherwise better protect the public health. At the same time, certain proposals could foster the availability of therapeutic agents of no human health consequence.

Sincerely,

Jesse Chappell

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President

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